No. 17-1484

In the Supreme Court of the United States

ALEX M. AZAR II, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

ALLINA HEALTH SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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Respondents argue that the D.C. Circuit's interpretation of Section 1395hh's notice-and-comment rulemaking provisions does not warrant further review for two reasons: first, they contend that the factual context here narrows the panel's holding; and, second, they contend that the decision below independently rests on a holding about Section 1395hh(a)(4) that the government has not properly challenged. Both contentions are flawed.

1. a. The D.C. Circuit created a conflict warranting review by holding that Section 1395hh's notice-and-comment procedures apply to interpretive rules. Pet. 14-15. The D.C. Circuit itself stated that it "respectfully disagree[d]" and was "breaking with several other courts of appeals." Pet. App. 17a.

Respondents do not deny that acknowledged conflict. They instead assert (Br. in Opp. (Br.) 24-25) that the conflict is "undeveloped" and "does not warrant" review in the "specific" context here involving "Medicare

fractions." But the acknowledged conflict over the application of Section 1395hh's notice-and-comment requirements to interpretive rules is not diminished because other circuits have addressed interpretive materials not involving Medicare fractions. The D.C. Circuit found it dispositive that agency contractors are required to follow agency instructions when making *initial* reimbursement decisions—even though those instructions are not binding on administrative review—and that those instructions change (or establish) a practice affecting Medicare payments. Pet. App. 12a-14a. Nothing in those holdings turns on any fact-bound feature of Medicare fractions. Nor is it significant that the D.C. Circuit declined to decide whether the agency's interpretation embodied in its Medicare-fraction calculations "constituted an APA interpretive rule." Br. 25. The D.C. Circuit assumed the question *arguendo* by ruling against the government on the ground that, even if the fractions constituted an interpretive rule, they would still require notice-and-comment rulemaking. Pet. App. 15a; see *id.* at 12a-14a. That holding was dispositive below and warrants review.

Respondents contend (Br. 26-27) that the circuit conflict is not "mature." But they do not deny that the conflicting holdings of other courts of appeals would bind future panels of those courts. Respondents, for instance, note that the Ninth Circuit in *Erringer* v. *Thompson*, 371 F.3d 625, 633 (2004), stated that it did not have to address the "possibility" that the Medicare Act might draw "the line between substantive and interpretive rules in a different place than the APA" because the interpretive rule at issue was "not close" to the line. But that statement does not alter *Erringer*'s holding that

Section 1395hh does not require notice-and-comment rulemaking for interpretive rules. *Ibid.*; see Pet. 14-15.

Furthermore, review is particularly warranted here because universal venue for providers' Medicare actions lies in the D.C. Circuit. Pet. 23. Respondents offer no relevant response. The monetary stakes and hospitals' legal sophistication will likely lead to future cases raising similar issues being litigated in the District of Columbia, where the decision below constitutes binding precedent. Indeed, after the decision below, providers filed about 30 similar Medicare cases in the District of Columbia, most of which have been stayed pending the disposition of this petition.

b. Certiorari is also warranted because the D.C. Circuit's interpretation of Section 1395hh's rulemaking provisions, if applied to the entire Medicare program, would impair the government's ability to administer its reimbursement process. Requiring the agency to conduct notice-and-comment rulemaking before it can establish or modify provisions of the Provider Reimbursement Manual (PRM) and other interpretive materials that Medicare contractors must follow would make it much more difficult for HHS to administer the Medicare program. Pet. 19-20.

Respondents contend (Br. 32-36) that the D.C. Circuit's decision concerning the particular Medicare fraction dispute here does not have prospective significance given the separate notice-and-comment rule effective FY2014. Even for the period from FY2005 to FY2013, however, the Medicare-fraction issue alone governs $3 to $4 billion in funding. Pet. 23 & n.13.[1] In any event,

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[1] Respondents do not dispute the accuracy of the estimate. About 2700 hospitals obtain DSH payments, and respondents' claim

respondents do not deny that, under the decision below, PRM provisions and other interpretive guidance addressing payment issues not directly controlled by statute or notice-and-comment regulations would constitute "requirements" establishing or changing "substantive legal standards" and require notice-and-comment rulemaking. Indeed, a mere three days after that decision, respondents' counsel argued that "cost report instructions" in the PRM interpreting regulatory requirements could not be properly followed, because, under the D.C. Circuit's binding precedent in this case, they constitute "requirement[s]" modifying Medicare standards that must be promulgated through Section 1395hh notice-and-comment rulemaking, which has no exception for "interpretive rules." Pl. Summ. J. Mem. at 30 & n.4, *Rocky Mountain Health Maint. Org., Inc.* v. *Price*, No. 17-cv-242 (D.D.C. July 28, 2017); see Pl. Opp. to Gov't Mot. for Summ. J. at 19-20, *Rocky Mountain*, *supra* (Nov. 1, 2017); see also, *e.g.*, Pls. Summ. J. Mem. at 24-26, *HealthAlliance Hosps., Inc.* v. *Wright*, No. 17-cv-917 (D.D.C. Oct. 2, 2017) (similar rulemaking argument by respondents' counsel).[2]

In illustrating the practical difficulties posed by the decision below, the petition explains that if the court of appeals were correct that the agency's calculation of FY2012 Medicare fractions (counting Part C days) "change[d] a substantive legal standard," then the

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$48.5 million in additional reimbursement for just nine hospitals for one year. Pet. App. 59a-61a.

[2] Respondents suggest (Br. 2-3, 35) that notice-and-comment rulemaking is not a significant hurdle because Congress requires it in certain Medicare contexts. That disregards the much broader scope of rulemaking that would be required for all interpretive guidance under the logic of the decision below.

agency's earlier calculation of such fractions (omitting Part C days) must have also "established" the standard in the first instance, 42 U.S.C. 1395hh(a)(2), such that notice-and-comment rulemaking was required before either practice could be followed. Pet. 20-21. The agency thus could not have calculated any Medicare fractions after the 1997 enactment of Medicare Part C without notice-and-comment rulemaking, notwithstanding the obvious need to discharge its obligation to calculate those fractions annually to administer Medicare's reimbursement regime and notwithstanding that providers may challenge those fractions, which—like other initial cost-reporting determinations—are not binding on administrative or judicial review. *Ibid.*; see pp. 6-7, *infra*.

Respondents deny that result by arguing (Br. 7-8, 30-31) that 42 C.F.R. 412.106(b)(2)(i) (2003) had already established the "substantive legal standard" by "unambiguously exclud[ing]" Medicare Part C days. Respondents miss the point and are wrong. They miss the point because the logic of the decision below would apply to any context in which the agency gives its contractors interpretive instructions about making initial reimbursement decisions. They are wrong because, as the D.C. Circuit has determined, "[p]rior to 2004, the regulation did not specify where [Part C] enrollees should be counted." *Northeast Hosp. Corp.* v. *Sebelius*, 657 F.3d 1, 14 (2011); cf. Pet. 7-8.[3] And because the regulation

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[3] The regulation included in the Medicare fraction "the number of covered patient days" "furnished to *patients* who * * * were entitled to both Medicare Part A and SSI." 42 C.F.R. 412.106(b)(2)(i) (2003) (emphasis added). Because Part C patients must be "entitled to benefits under [P]art A," 42 U.S.C. 1395w-21(a)(3)(A), it was at least ambiguous whether Section 412.106(b)(2)(i) was properly interpreted as counting Part C days in that fraction. See Pet. 4-5.

did not unambiguously resolve the issue, the agency's initial calculations—under the panel's reasoning—would have "established" a substantive legal standard requiring notice-and-comment rulemaking whether they included or excluded Part C days. That result and the prospect of its application across the Medicare program underscore the need for review.

c. Respondents offer little response to the petition's arguments that the statutory term "substantive legal standard" limits Section 1395hh(a)(2) to substantive (not interpretive) rules imposing legal standards that bind the agency on administrative review, see Pet. 15-18; and that the term "requirements" is limited to provisions that bind not only Medicare contractors, but also the agency itself on review, see Pet. 18-19.

Instead, respondents rest on arguments that were largely not addressed or relied upon by the court of appeals. For instance, respondents erroneously assert (Br. 33-34) that the Medicare fractions *are* "binding" on review. Respondents cite a regulation that merely instructs *contractors* making *initial* determinations to "add[]" a CMS-calculated Medicare fraction to their own calculations, 42 C.F.R. 412.106(b)(2) and (5). But if the provider seeks agency review, the fraction (like the rest of the initial decision) has no binding force. Pet. 5-6. Thus, contrary to respondents' suggestion (Br. 34), the D.C. Circuit held that the PRRB correctly declined to address the fractions here not because they were themselves binding on the PRRB, but because respondents *argued* that the "fractions constituted a new regulation" that was "procedurally [in]valid" and that the PRRB lacked authority to decide that question. Pet. App. 11a.

Respondents rely (Br. 28) on Section 1395hh(b)(2)'s express incorporation of the APA's good-cause provision

(5 U.S.C. 552(b)(B)) and the absence of an interpretive-rule exemption like that in 5 U.S.C. 552(b)(A). But the APA's notice-and-comment requirement is worded generally, applying to all "rules," so an express exemption for "interpretative" rules was necessary. In Section 1395hh, in contrast, the term "substantive legal standard" itself excludes interpretive rules. Pet. 15-18. Moreover, when Congress enacted Section 1395hh(b)'s cross-reference to the APA's good-cause exception, the Conference Report emphasized that the notice-and-comment provisions would not apply to "interpretive rules." H.R. Conf. Rep. No. 1012, 99th Cong., 2d Sess. 311 (1986).

Respondents note (Br. 29 n.7) that HHS's predecessor agency chose in 1971 to voluntarily "follow the APA['s]" rulemaking requirements, even though the APA itself exempted Medicare's "benefits" program from them, 5 U.S.C. 553(a)(2). See *Humana of S.C., Inc.* v. *Califano*, 590 F.2d 1070, 1082, 1084 & n.103 (D.C. Cir. 1978). Respondents suggest (Br. 29) that there is no "reason why Congress [would have] adopted particular requirements in [Section 1395hh] only to restate there what the APA already required." Respondents are wrong. Congress enacted Section 1395hh's rulemaking requirements because of concerns that HHS would abandon that practice.

In 1982, in a proposed rulemaking, HHS stated that although it "ordinarily" would "use notice and comment procedures" for "Medicare," "even though such action is not required by the [APA]," its "voluntary" policy did not "create any right or benefit enforceable at law," and it would *not* use APA rulemaking where it deemed the costs to "outweigh" the benefits. 47 Fed. Reg. 26,860, 26,860-26,861 (June 22, 1982) (proposing 45 C.F.R. 2.2(c)). In response, a "broad-based coalition" recommended

that Congress require HHS "to follow the procedures delineated in the APA (including notice of proposed rulemaking) when issuing any regulation or rule relating to Medicare." *Medicare Appeals Provisions: Hearing on S. 1158 Before the Subcomm. on Health of the Senate Comm. on Finance*, 99th Cong., 1st Sess. 25-26 (1985). In light of HHS's "proposed regulation," numerous stakeholders told Congress that "the time ha[d] come to make it clear, *by statute*, that Medicare regulations * * * should be subject to the [APA]." *Id.* at 62; see *id.* at 119-120 & n.14, 149, 211, 239-240. That was deemed necessary because of the perception that HHS had "abandoned" its prior "voluntary commitment to subject Medicare to the APA." *E.g.*, *Examination of Quality Care Under Medicare's Prospective Payment System: Hearing Before the Senate Comm. on Finance*, 99th Cong., 2d Sess. 346-347 (1986).

Respondents erroneously rely (Br. 5-6, 37) on a House Report that accompanied different and broader statutory text, see H.R. Rep. No. 391, 100th Cong., 1st Sess. 430, 594-595 (1987), that Congress later rejected by limiting Section 1395hh(a)(2) "only" to matters establishing or changing a relevant "substantive legal standard." H.R. Conf. Rep. No. 495, 100th Cong., 1st Sess. 566 (1987); see *id.* at 82. That change was designed to "reflect[] recent court rulings," *id.* at 566, and the only extant rulings at that time were those applying the *APA*'s requirements. Thus, in *American Hospital Ass'n* v. *Bowen*, 834 F.2d 1037, 1045, 1055-1057 & n.4 (1987), the D.C. Circuit held that although notice-and-comment rulemaking was necessary for "substantive rule[s]" having legal force, it was not necessary for "in-

terpretive rules" binding on private contractors assisting HHS in the administration of the Medicare program, because they did not change "substantive standards."

2. Respondents argue (Br. 18-22) that certiorari is unwarranted because the D.C. Circuit also based its decision on Section 1395hh(a)(4). That contention lacks merit. As discussed below, the D.C. Circuit did not rely on Section 1395hh(a)(4) as an independent basis for the decision below, because it applies only to a "regulation" governed by Section 1395hh(a)(2).

a. If an agency's "notice and comment" process is defective because a final rule is not a logical outgrowth of the proposal and if equity requires it, the "unlawfully promulgated regulation" ordinarily "can be left in place while the agency provides the proper procedural remedy." *Fertilizer Inst.* v. *EPA*, 935 F.2d 1303, 1312 (D.C. Cir. 1991). As respondents acknowledge, Section 1395hh(a)(4) "suppl[ies] an exception to th[at] doctrine, Br. 23 n.4, by prohibiting such a "regulation" from "tak[ing] effect" pending the agency's resolution of the procedural defect, 42 U.S.C. 1395hh(a)(4).

A "regulation" under Section 1395hh(a)(4) is the same type of "regulation" that Section 1395hh(a)(2) earlier defines as a rule, requirement, or statement of policy that establishes or changes a relevant "substantive legal standard." Section 1395hh(a)(4)'s no-effect provision, which is triggered only when a prior notice-and-comment process is deemed defective, logically applies only if the "regulation" in question is itself a binding "regulation" for which Section 1395hh(a)(2) required notice-and-comment rulemaking in the first instance. Indeed, where, as here, an agency applies a non-binding interpretation to facilitate an initial Medicare determi-

nation, no earlier "regulation" has "take[n] effect" because, if it had, the regulation would have also been *binding* on administrative review. Thus, because Section 1395hh(a)(2)'s application to "substantive legal standards" does not apply to agency interpretive provisions, Pet. 15-17, the certiorari petition explains that Section 1395hh(a)(4) does not apply "where Section 1395hh would not [have] require[d] such rulemaking for a (non-binding) interpretive action by CMS in the first place." Pet. 22.

Respondents counter (Br. 18) that the court of appeals' Section 1395hh(a)(4) holding was independent of its Section 1395hh(a)(2) holding merely because the court stated that HHS would not prevail "even if [it] were correct that the [latter] somehow incorporated the APA's notice-and-comment exception for interpretive rules." Pet. App. 17a-18a. The court, however, treated the argument that Section 1395hh "incorporate[s] the APA's interpretive-rule exception" in 5 U.S.C. 553(b)(A), see Pet. App. 15a-16a, as *distinct* from the argument that the non-binding interpretation here is not a "requirement" changing a "substantive legal standard" that would constitute a "regulation" under Section 1395hh(a)(2), *id.* at 12a-14a. Thus, while the court said that its Section 1395hh(a)(4) holding would apply if Section 1395hh incorporated the APA's separate exception for interpretive rules, it did *not* say that Section 1395hh(a)(4) would apply even if the challenged Medicare interpretation is not a "regulation" covered by Section 1395hh(a)(2). To the contrary, the court reasoned that Section 1395hh(a)(4) applied *precisely because* it thought the agency was making the "regulation" that was previously vacated "legally operative," *id.* at 18a, which obviously would not be true if the agency interpretation was not a "rule"

or "requirement" governed by Section 13955hh(a)(2). Reversal of the Section 1395hh(a)(2) holding would thus logically compel reversal of the Section 1395hh(a)(4) holding.

b. Respondents argue (Br. 20-21) that the government's question presented does not encompass the D.C. Circuit's Section 1395hh(a)(4) holding, because that question refers to Section 1395hh(a)(2). But for the reasons above, the Section 1395hh(a)(4) holding rests upon the court's interpretation of Section 1395hh(a)(2) and thus is "fairly included" by the question presented challenging that interpretation. Sup. Ct. R. 14.1(a). In any event, this is not a case where the certiorari petition fails adequately to identify an issue it seeks to bring before the Court. Respondents fully understood and addressed our argument (Pet. 22) concerning Section 1395hh(a)(4). Thus, if this Court were to conclude that the question presented could be clarified by also explicitly referring to Section 1395hh(a)(4), it would be appropriate for the Court to do so in the course of granting review of the question concerning the D.C. Circuit's interpretation of Section 1395hh as requiring notice-and-comment rulemaking. That interpretation warrants this Court's review.

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For the foregoing reasons and those stated in the petition for a writ of certiorari, the petition should be granted.

Respectfully submitted.

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Solicitor General

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